

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2174399	(X3) Date Survey Completed 11/16/2023
Name of Provider or Supplier Carolinas Fertility Institute, Pa	Street Address, City, State 2159 Hendersonville Road, Suite 30, Arden, NC	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D6086	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii)</p> <p>The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.</p> <p>This STANDARD is not met as evidenced by: Based upon the absence of documentation and interviews with TP (Testing Personnel) #1 and the LD (Laboratory Director) on 11/16/23, the Laboratory Director failed to ensure the accuracy of semen analyses performed in the Asheville laboratory prior to the initiation of patient testing. Findings: Review of laboratory records revealed the absence of documentation that the laboratory verified the accuracy of semen analyses performed in the laboratory of this Asheville facility prior to the initiation of patient testing. In interview at approximately 9:30 a.m., TP #1 confirmed she was not employed at the clinic when patient testing was first initiated. In interview at approximately 9:45 a.m., the LD stated that he thought a method validation may have been performed at a different affiliated location.</p>